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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/689,359

10/20/2003

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KBI-0015

4537

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09/17/2007

EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

09/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/689,359

Applicant(s)

RANGANATHAN, NATARAJAN

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response filed on July 5, 2007 have been received and entered into the case. Claim 11 is canceled; claims 1 – 10 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 – 5, 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul in view of Cavalier Vesely et al. (US 5716615), Brassart et al. (US 5494664) and/or Fridman (US 3950544).

Applicant claims to a nutritional food or product comprising *S. thermophilus*, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient, wherein the composition has a water activity of less than 0.47. The carbohydrate, fat, and protein are each selected from a list. The composition may further comprise at least one probiotic and/or at least one prebiotic, each selected from a list. Applicant finally claims a method for restoring and maintaining gastrointestinal (GI) health, comprising administering to a

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subject at least one food or nutritional product comprising an effective amount of probiotic bacteria and an effective amount of a prebiotic; and a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and an ammoniaphilic urea-degrading microorganism with pH stability and urea degrading activity.

Paul teaches compositions for restoring and maintaining GI health, comprising immunogloblins (protein), FOS (prebiotic), pectin (prebiotic), beneficial human intestinal microorganism (abstract, col.5 line 60-65), wherein the compositions are powdered (col.13-14). The immunoglobulin, or protein, is derived from milk or whey (abstract); and the bacteria may be *Lactobacillus acidophilis*, *L. bulgaricus*, *L. casei*, *L. fermentum*, *L. salivaroës*, *L. brevis*, or *L. plantarum*, or *Bifidobacterium adolescentis*, *B. infantis*, *B. longum*, *B. thermophilis*, *B. bifidum*, (col.4 line 20-29) or Streptococci (col.9 line 44-50). The composition further comprises carbohydrates such as maltodextrin and lactose, and lipids such as lecithin (col.5 line 40-45). Paul additionally teaches methods for restoring and maintaining GI health, comprising administering the composition (col.4 line 40-45).

Although Paul does not specifically teach that the bacteria are ammoniaphilic urea-degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria are the same as those claimed. The bacteria of the cited reference must also, intrinsically, have the same characteristics.

Paul does not specifically teach the beneficial bacteria to include *S. thermophilus*. However, at the time of the claimed invention, *S. thermophilus* was a known and used bacteria, effective to benefit the GI tract. In support, Cavaliere Vesely teaches pharmaceutical compositions containing *S. thermophilus*, wherein the composition is effective to treat GI

disorders (abstract). In addition, Brassart (abstract, col.3-4) and Fridman (col.3-4) both teach nutritional compositions wherein they contain microbes beneficial to the GI tract such as *S. thermophilus*. At the time of the claimed invention, one of ordinary skill in the art would have been motivated to use *S. thermophilus* in the composition of Paul, as it was a known and used bacteria beneficial to the GI tract, as evidenced by the supporting references.

Paul does not teach the claimed amounts of each component or wherein the water content is less than about 0.47. However, Paul teaches that the composition of the mixture may be varied (column 4, lines 1-52; and column 13, line 47, through column 14, line 38). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition. Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

3. Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul in view of Cavaliere Vesely, Brassart and/or Fridman, and further in view of Halpin-Dohnalek.

Applicant claims to a nutritional food or product comprising *S. thermophilus*, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient, wherein the composition has a water activity of less than 0.47. The additional probiotic bacteria, carbohydrate, fat, and protein are each selected from a list; the product provides 5 – 20 billion CFUs; the carbohydrate is selected from a list; and the composition

further comprises at least one vitamin and mineral. Applicant additionally claims a food product comprising carbohydrates, 2 – 12% fat, protein, vitamin, mineral, probiotic and probiotic wherein the composition has a water activity of less than about 0.47. Applicant finally claims a method for restoring and maintaining gastrointestinal (GI) health, comprising administering to a subject at least one food or nutritional product comprising an effective amount of probiotic bacteria and an effective amount of a prebiotic; and a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and an ammoniaphilic urea-degrading microorganism with pH stability and urea degrading activity.

Paul teaches compositions for restoring and maintaining GI health, comprising immunogloblins (protein), FOS (prebiotic), pectin (prebiotic), beneficial human intestinal microorganism (abstract, col.5 line 60-65), wherein the compositions are powdered (col.13-14). The immunoglobulin, or protein, is derived from milk or whey (abstract); and the bacteria may be *Lactobacillus acidophilis*, *L. bulgaricus*, *L. casei*, *L. fermentum*, *L. salivaroës*, *L. brevis*, or *L. plantarum*, or *Bifidobacterium adolescentis*, *B. infantis*, *B. longum*, *B. thermophilis*, *B. bifidum*, (col.4 line 20-29) or Streptococci (col.9 line 44-50). The composition further comprises carbohydrates such as maltodextrin and lactose, and lipids such as lecithin (col.5 line 40-45). Paul additionally teaches methods for restoring and maintaining GI health, comprising administering the composition (col.4 line 40-45). Although Paul does not specifically teach that the bacteria are ammoniaphilic urea-degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria are the same as those claimed. The bacteria of the cited reference must also, intrinsically, have the same characteristics.

Paul does not specifically teach the beneficial bacteria to include *S. thermophilus*. However, at the time of the claimed invention, *S. thermophilus* was a known and used bacteria, effective to benefit the GI tract. In support, Cavaliere Vesely teaches pharmaceutical compositions containing *S. thermophilus*, wherein the composition is effective to treat GI disorders (abstract). In addition, Brassart (abstract, col.3-4) and Fridman (col.3-4) both teach nutritional compositions wherein they contain microbes beneficial to the GI tract such as *S. thermophilus*. At the time of the claimed invention, one of ordinary skill in the art would have been motivated to use *S. thermophilus* in the composition of Paul, as it was a known and used bacteria beneficial to the GI tract, as evidenced by the supporting references.

Halpin-Dohnalek teaches a powdered nutritional composition comprising protein, fat, carbohydrates and the probiotic bacteria *Lactobacillus reuteri*, *L. acidophilis* and *Bifidobacterium infantis* (abstract). The reference teaches that the composition is useful for maintaining GI health, and teaches a method for restoring GI health by administering the composition (abstract). The compositions further comprise minerals and vitamins (col.3 line 30-50) as well as sucrose (claims). Halpin-Dohnalek provides examples of the composition wherein the compositions provide 10×10^9 – 5×10^9 (or 5 – 10 billion) CFUs of *L. reuteri* (example 1).

The references do not teach the all of the ingredients together in a single composition in the claimed amounts, with the claimed water activity. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Furthermore, the references teach that the composition of their mixture may be varied (Halpin-Dohnalek, column 4, lines 1-28; Paul,

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column 4, lines 1-52; and column 13, line 47, through column 14, line 38) and wherein the composition is a powder (Halpin-Dohnalek, abstract). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition.

This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant argues that the references do not teach *S. thermophilus*.

However, this argument fails to persuade because as stated in the rejections above, it would have been obvious to include *S. thermophilus* in the composition of Paul, as it was known and used in the art for compositions benefiting the GI tract.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

September 13, 2007